



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 30 1998

Mr. Hank Schriel
Director
Health Canada
Information Access and Coordination Division
9th Floor Brooke Claxton Building Tunney's Pasture
Ottawa, Ontario
Canada
K1A 0K9

Dear Mr. Schriel:

This letter is in reference to the "RBST (NutraLac) 'Gaps Analysis' Report by rBST Internal Review Team." Last week, appendices from that document were submitted to the Food and Drug Administration's public docket for a citizen petition concerning recombinant bovine growth hormone. Because some of the information in those appendices appeared to be confidential, a member of my staff, Carol Haley, called Dr. George Paterson in the Food Directorate on December 29, 1998, to determine whether the appendices had been made available to the public. Dr. Paterson said that they had. CVM's Freedom of Information staff has recommended that we obtain written confirmation of that fact.

Enclosed is a copy of the appendices that were submitted to FDA's public docket. We would appreciate your providing us with written confirmation that the records contained in the enclosed package were indeed released to the public in Canada. We have removed the appendices from the docket until we can confirm that the information has been made available to the public in Canada.

Please feel free to contact Dr. Haley if you have any questions. She can be reached at 301-594-1682.

Sincerely yours,

Stephen F. Sundlof, D.V.M., Ph.D.
Director, Center for Veterinary Medicine

Enclosure

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